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10/645,915	08/21/2003	Christopher Marrs	NEU-5006	9584

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EXAMINER	
VAKILI, ZOHREH	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,915	MARRS, CHRISTOPHER	
	Examiner	Art Unit	
	Zohreh Vakili	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *2-5,7,12-15 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,8-11,16,17,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/12/2005 and 01/24/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are presented for examination.

Applicant's election of the species for plant extract is chaparral extract, and the oxygen labile active agent is retinol reply filed on May 7, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, Applicant elects claims 2-5, 7, 12-15, and 18 are withdrawn from consideration as being directed to non-elected subject matter. Claims 1, 6, 8-11, 16, 17, and 19-20 read on the elected invention and are herein examined on the merits.

Applicant's Information Disclosure Statements (IDS) filed 12/12/2005 and 01/24/2006 have been received and entered into the application.

Claim Rejections - 35 USC § 112, First Paragraph

LACK OF WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses extracts of plants, such as extracts comprising of lapacho, cranberry, and chaparral, oxygen labile agents such as retinol which meet the written description and enablement provisions of 35 USC 112, first paragraph.

However, claims 11 and 17 are directed to encompass isoascorbic acid derivatives and tocopherol derivatives, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these derivatives, meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath, Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of

isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.,* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli,* 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first

paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6, 8-11, 16-17, and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad (U.S. Patent No. 6630163 B1) and in view of Yusuf et al. (U.S. Patent No. 5583136).

Murad teaches some non-enzymatic antioxidants, such as Vitamin E (tocopherol), Vitamin A (beta-carotene), and Vitamin C (ascorbic acid) have each been individually applied to assist the skin in scavenging free radicals and neutralizing the harmful effects of UV light. (see col. 1, lines 44-49). Also, an herbal supplement and nutritional suggestions for the maintenance of the skin are disclosed. The herbal supplement consists of extracts of chaparral, dandelion root, burdock root, licorice root, echinacea, yellow dock root, kelp and cayenne (see col. 5, lines 64-67 & col. 6, lines 1-

3). The additional pharmaceutical composition may be a moisturizing agent provided in an amount sufficient to facilitate hydration of the skin. The moisturizer may be a mono- or poly-hydroxy acid, a hydrophobic agent or a hydrophilic agent. The mono- or poly-hydroxy acid may be glycolic acid, lactic acid, citric acid, tannic acid, salicylic acid, or a mixture thereof. The hydrophobic agent may be ceramide, borage oil, tocopherol linoleate, dimethicone, glycerine, or a mixture thereof (see col. 6, lines 38-50). In a preferred embodiment of the pharmaceutical composition, the fruit extract is present in an amount from about 0.01 to 80 weight percent, preferably from about 0.1 to 20 weight percent, and more preferably from about 0.5 to 10 weight percent. Any fruit extract capable of preventing treating or managing skin disorders and/or skin damage is suitable for use in the dermatological agents and methods of the invention. The fruit extract may be obtained from any part of the plant including, for example, the fruit, the skin or rind of the fruit, the seeds, the bark, the leaves, the roots, or the stem (see col. 8, lines 13-29). Moisturizing agents that are hydrophobic agents include, but are not limited to, ceramide, borage oil (linoleic acid), tocopherol linoleate, dimethicone, glycerine, and mixtures thereof. Hydrophobic agents, when present, are believed to moisturize the skin by inhibiting or preventing the loss of water from the skin. The hydrophobic agent, when present, is typically present in an amount from about 0.01 to 2 weight percent, preferably from about 0.05 to 1.5 weight percent, and more preferably from about 0.1 to 1 weight percent of the composition (see col. 10, lines 28-37).

Yusuf et al. teach skin care compositions comprising a water-in-oil emulsion base containing retinoids and at least one imidazole in a free base form and possessing good physical and chemical stability (see abstract). The water-soluble antioxidants which are useful in the compositions of the present invention include ascorbic acid, sodium sulfite, sodium metabisulfite, sodium bisulfite, sodium thiosulfite, sodium formaldehyde sulfoxylate, isoascorbic acid, and mixtures thereof as well as any other known water-soluble antioxidant compatible with the other components of the compositions (see col. 6, lines 18-26). The oil-soluble antioxidants which are useful in the compositions of the present invention include butylated hydroxytoluene (BHT), ascorbyl palmitate, butylated hydroxyanisole (BHA), alpha-tocopherol, and mixtures thereof as well as any other known oil-soluble antioxidant compatible with the other components of the compositions (see col. 6, lines 27-34). The antioxidants should be utilized in a stabilizing effective amount and may range in total from about 0.001 to 5.0% based on the weight of the total composition, preferably from about 0.01 to 1.0%. The amount of antioxidants utilized in the compositions of the present invention is dependent in part on the specific antioxidants selected, the amount of and specific retinoid being protected and the processing conditions (see col. 6, lines 35-42). The retinoid compounds which are useful in the compositions of the present invention consist of Vitamin A alcohol (retinol), Vitamin A aldehyde (retinal) and Vitamin A esters (retinyl acetate and retinyl palmitate). These retinoids are utilized in the compositions of the present invention in a therapeutically effective amount that may range from

about 0.001 to 5.0% by weight of the total compositions, preferably from about 0.001 to 1.0% (see col. 6, lines 58-65).

It is obvious to one of ordinary skill in the art to use a combination of the composition taught by Murad with the skin care composition taught by Yusuf et al. Murad teaches the extract of herbs/fruits along with tocopherol in the composition and he also presents the same range of concentration for the plant extract and tocopherol. Yusuf et al. teach a skin care composition containing retinoids, retinol, isoascorbic acid, and tocopherol with the same claimed concentration range.

It would have been obvious to have combined the teachings of Murad and Yusuf et al. and would have been motivated to combine the references because both references combined teach the claimed invention. One would have been motivated to use these two teachings of both compositions that are directed to skin care and treatment and arrive to the claimed composition.

Thus the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and as a whole, prima facie obvious.

Conclusion

No claims of the present application are allowed.

Any inquiry concerning this communication should be directed to Zohreh Vakili, telephone number 571-272-3099. The examiner can normally be reached from 8:30 a.m. to 5:00 p.m., Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili
Patent Examiner
Art Unit 1614

June 7, 2007

ZV

11 JUNE 2007

6/11/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER